Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- Mandatory – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- Non-harmonized – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

EPIC-26 Short Form (Expanded Prostate Cancer Index Composite-26) CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

N/A

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- QS – Questionnaires (v3.3)

EPIC-26 Short Form (Expanded Prostate Cancer Index Composite-26) CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - How Often Have You Leaked Urine Score 5 Point Scale (Short form (EPIC-26)) 7204050 EPIC101	Person's stated observation in the past 4 weeks how often they have leaked urine, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC101, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 1 of 26	NUMBER. Use choice list.
EPIC-26 - Best Describes Urinary Control Score 4 Point Scale (Short form (EPIC-26)) 7294051 EPIC102	Person's stated observation in the past 4 weeks of their urinary control, using a 4 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC102, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 2 of 26	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Pads or Adult Diapers per Day Score 4 Point Scale (Short form (EPIC-26)) 7204052 EPIC103	Person's stated observation in the past 4 weeks how many pads or adult diapers per day did they use to control leakage, using a 4 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC103, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 3 of 26	NUMBER. Use choice list.
EPIC-26 - Dripping or Leaking Urine Score 5 Point Scale (Short form (EPIC-26)) 7074839 EPIC104A	Person's stated observation in the past 4 weeks how big a problem dripping or leaking urine has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 4 of 26; How big a problem, if any, has each of the following been for you during the last 4 weeks?	NUMBER. Use choice list.
EPIC-26 - Pain or Burning on Urination Score 5 Point Scale (Short form (EPIC-26)) 7074779 EPIC104B	Person's stated observation in the past 4 weeks how big a problem pain or burning on urination has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 5 of 26; How big a problem, if any, has each of the following been for you during the last 4 weeks?	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Bleeding With Urination Score 5 Point Scale (Short form (EPIC-26)) 7204054 EPIC104C	Person's stated observation in the past 4 weeks how big a problem bleeding with urination has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104C, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 6 of 26; How big a problem, if any, has each of the following been for you during the last 4 weeks?	NUMBER. Use choice list.
EPIC-26 - Weak Urine Stream or Incomplete Emptying Score 5 Point Scale (Short form (EPIC-26)) 7204053 EPIC104D	Person's stated observation in the past 4 weeks how big a problem weak urine stream or incomplete emptying has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104D, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 7 of 26; How big a problem, if any, has each of the following been for you during the last 4 weeks?	NUMBER. Use choice list.
EPIC-26 - Urinate Frequently During the Day Score 5 Point Scale (Short form (EPIC-26)) 7074700 EPIC104E	Person's stated observation in the past 4 weeks how big a problem the need to urinate frequently during the day has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104E, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 8 of 26; How big a problem, if any, has each of the following been for you during the last 4 weeks?	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Overall Problem Urinary Function Score 5 Point Scale (Short form (EPIC-26)) 7074713 EPIC105	Person's stated observation in the past 4 weeks overall how big a problem urinary function has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC105, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 9 of 26	NUMBER. Use choice list.
EPIC-26 - Urgency to Have Bowel Movement Score 5 Point Scale (Short form (EPIC-26)) 7074731 EPIC106A	Person's stated observation in the past 4 weeks how big a problem urgency to have bowel movements has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 10 of 26; How big a problem, if any, has each of the following been for you?	NUMBER. Use choice list.
EPIC-26 - Increased Frequency of Bowel Movements Score 5 Point Scale (Short form (EPIC-26)) 7074835 EPIC106B	Person's stated observation in the past 4 weeks how big a problem increased frequency of bowel movements has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 11 of 26; How big a problem, if any, has each of the following been for you?	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Losing Control of Stools Score 5 Point Scale (Short form (EPIC-26)) 7204055 EPIC106C	Person's stated observation in the past 4 weeks how big a problem losing control of stools has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106C, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 12 of 26; How big a problem, if any, has each of the following been for you?	NUMBER. Use choice list.
EPIC-26 - Bloody Stools Score 5 Point Scale (Short form (EPIC-26)) 7204056 EPIC106D	Person's stated observation in the past 4 weeks how big a problem bloody stools have been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106D, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 13 of 26; How big a problem, if any, has each of the following been for you?	NUMBER. Use choice list.
EPIC-26 - Abdominal or Pelvic or Rectal Pain Score 5 Point Scale (Short form (EPIC-26)) 7204212 EPIC106E	Person's stated observation in the past 4 weeks how big a problem abdominal, pelvic or rectal pain has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106E, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 14 of 26; How big a problem, if any, has each of the following been for you?	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Overall Problem Bowel Habits Score 5 Point Scale (Short form (EPIC-26)) 7074845 EPIC107	Person's stated observation in the past 4 weeks overall how big a problem their bowel habits have been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC107, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 15 of 26	NUMBER. Use choice list.
EPIC-26 - Losing Control of Stools Score 5 Point Scale (Short form (EPIC-26)) 7204057 EPIC108A	Person's stated observation in the past 4 weeks their ability to have an erection, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC108A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 16 of 26; How would you rate each of the following during the last 4 weeks?	NUMBER. Use choice list.
EPIC-26 - Ability to Reach Orgasm Score 5 Point Scale (Short form (EPIC-26)) 7204058 EPIC108B	Person's stated observation in the past 4 weeks their ability to have reach orgasm (climax), using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC108B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 17 of 26; How would you rate each of the following during the last 4 weeks?	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Quality of Erections Score 4 Point Scale (Short form (EPIC-26)) 7074774 EPIC109	Person's stated observation in the past 4 weeks their usual quality of their erections, using a 4 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC109, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 18 of 26	NUMBER. Use choice list.
EPIC-26 - Frequency of Erections Score 5 Point Scale (Short form (EPIC-26)) 7074727 EPIC110	Person's stated observation in the past 4 weeks their frequency of erections, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC110, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 19 of 26	NUMBER. Use choice list.
EPIC-26 - Ability to Function Sexually Score 5 Point Scale (Short form (EPIC-26)) 7074717 EPIC111	Person's stated observation in the past 4 weeks overall their ability to function sexually, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC111, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 20 of 26	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Overall Problem Sexual Function Score 5 Point Scale (Short form (EPIC-26)) 7204059 EPIC112	Person's stated observation in the past 4 weeks overall how big a problem their sexual function or lack of sexual function has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC112, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 21 of 26	NUMBER. Use choice list.
EPIC-26 - Hot Flashes Score 5 Point Scale (Short form (EPIC-26)) 7074704 EPIC113A	Person's stated observation in the past 4 weeks how big a problem hot flashes have been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 22 of 26; How big a problem during the last 4 weeks, if any, has each of the following been for you	NUMBER. Use choice list.
EPIC-26 - Breast Tender or Enlargement Score 5 Point Scale (Short form (EPIC-26)) 7204060 EPIC113B	Person's stated observation in the past 4 weeks how big a problem breast tenderness or enlargement has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 23 of 26; How big a problem during the last 4 weeks, if any, has each of the following been for you	NUMBER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
EPIC-26 - Feeling Depressed Score 5 Point Scale (Short form (EPIC-26)) 7204061 EPIC113C	Person's stated observation in the past 4 weeks how big a problem feeling depressed has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113C, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 24 of 26; How big a problem during the last 4 weeks, if any, has each of the following been for you	NUMBER. Use choice list.
EPIC-26 - Lack of Energy Score 5 Point Scale (Short form (EPIC-26)) 7204062 EPIC113D	Person's stated observation in the past 4 weeks how big a problem lack of energy has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113D, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 25 of 26; How big a problem during the last 4 weeks, if any, has each of the following been for you	NUMBER. Use choice list.
EPIC-26 - Change in Body Weight Score 5 Point Scale (Short form (EPIC-26)) 7204063 EPIC113E	Person's stated observation in the past 4 weeks how big a problem their change in body weight has been, using a 5 point Likert scale. CDASH: No Match; SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113E, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26; Question 26 of 26; How big a problem during the last 4 weeks, if any, has each of the following been for you	NUMBER. Use choice list.

Annotated CRF: EPIC-26 Short Form (Expanded Prostate Cancer Index Composite-26) CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: EPIC-26 Short Form (Expanded Prostate Cancer Index Composite-26) CDISC Aligned NCI Standard Template

Short form (EPIC-26) Questions

CRF Question	Value Domain
Over the past 4 weeks, how often have you leaked urine? (7204050) **CDE Short Name:** EPIC101 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC101, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – More than once a day ☐ 2 – About once a day ☐ 3 – More than once a week ☐ 4 – About once a week ☐ 5 – Rarely or never
Which of the following best describes your urinary control during the last 4 weeks? (7204051) **CDE Short Name:** EPIC102 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC102, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – No urinary control whatsoever ☐ 2 – Frequent dribbling ☐ 3 – Occasional dribbling ☐ 4 – Total control
How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks? (7204052) **CDE Short Name:** EPIC103 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC103, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – None ☐ 1 – 1 pad per day ☐ 2 – 2 pads per day ☐ 3 – 3 or more pads per day

CRF Question	Value Domain
Dripping or leaking urine (7074839) **CDE Short Name:** EPIC104A CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Pain or burning on urination (7074779) **CDE Short Name:** EPIC104B CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Bleeding with urination (7204054) **CDE Short Name:** EPIC104C CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104C, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Weak urine stream or incomplete emptying (7204053) **CDE Short Name:** EPIC104D CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104D, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem

CRF Question	Value Domain
Need to urinate frequently during the day (7074700) **CDE Short Name:** EPIC104E CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC104E, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Overall, how big a problem has your urinary function been for you during the last 4 weeks? (7074713) **CDE Short Name:** EPIC105 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC105, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Urgency to have a bowel movement (7074731) **CDE Short Name:** EPIC106A CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Increased frequency of bowel movements (7074835) **CDE Short Name:** EPIC106B CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem

CRF Question	Value Domain
Losing control of your stools (7204055) **CDE Short Name:** EPIC106C CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106C, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Bloody stools (7204056) **CDE Short Name:** EPIC106D CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106D, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Abdominal/Pelvic/Rectal pain (7204212) **CDE Short Name:** EPIC106E CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC106E, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Overall, how big a problem have your bowel habits been for you during the last 4 weeks? (7074845) **CDE Short Name:** EPIC107 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC107, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – No Problem ☐ 2 – Very Small Problem ☐ 3 – Small Problem ☐ 4 – Moderate Problem ☐ 5 – Big Problem

CRF Question	Value Domain
Your ability to have an erection? (7204057) **CDE Short Name:** EPIC108A CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC108A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – Very Poor to None ☐ 2 – Poor ☐ 3 – Fair ☐ 4 – Good ☐ 5 – Very good
Your ability to reach orgasm (climax)? (7204058) **CDE Short Name:** EPIC108B CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC108B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – Very Poor to None ☐ 2 – Poor ☐ 3 – Fair ☐ 4 – Good ☐ 5 – Very good
How would you describe the usual QUALITY of your erections during the last 4 weeks? (7074774) **CDE Short Name:** EPIC109 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC109, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – None at all ☐ 2 – Not firm enough for any sexual activity ☐ 3 – Firm enough for masturbation and foreplay only ☐ 4 – Firm enough for intercourse
How would you describe the FREQUENCY of your erections during the last 4 weeks? (7074727) **CDE Short Name:** EPIC110 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC110, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – I NEVER had an erection when I wanted one ☐ 2 – I had an erection LESS THAN HALF the time I wanted one ☐ 3 – I had an erection ABOUT HALF the time I wanted one ☐ 4 – I had an erection MORE THAN HALF the time I wanted one ☐ 5 – I had an erection WHENEVER I wanted one

CRF Question	Value Domain
Overall, how would you rate your ability to function sexually during the last 4 weeks? (7074717) **CDE Short Name:** EPIC111 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC111, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – Very Poor ☐ 2 – Poor ☐ 3 – Fair ☐ 4 – Good ☐ 5 – Very good
Overall, how big a problem has your sexual function or lack of sexual function been for you during the last 4 weeks? (7204059) **CDE Short Name:** EPIC112 CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC112, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 1 – No Problem ☐ 2 – Very Small Problem ☐ 3 – Small Problem ☐ 4 – Moderate Problem ☐ 5 – Big Problem
Hot flashes (7074704) **CDE Short Name:** EPIC113A CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113A, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0– No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Breast tenderness/enlargement (7204060) **CDE Short Name:** EPIC113B CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113B, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem

CRF Question	Value Domain
Feeling depressed (7204061) **CDE Short Name:** EPIC113C CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113C, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Lack of energy (7204062) **CDE Short Name:** EPIC113D CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113D, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem
Change in body weight (7204063) **CDE Short Name:** EPIC113E CDASH: No Match SDTM: QSORRES (6659628) where QSTESTCD (6659631) = EPIC113E, QSEVLINT (6659632) = -P4W and QSCAT (6648971) = EPIC-26	NUMBER – Maximum Length = 1 ☐ 0 – No Problem ☐ 1 – Very Small Problem ☐ 2 – Small Problem ☐ 3 – Moderate Problem ☐ 4 – Big Problem